

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
J. Richard Gyory

Confirmation No.: **7214**

Application No.: **10/814,705**

Group Art Unit: **3767**

Filing Date: **March 30, 2004**

Examiner: **Andrew M. Gilbert**

For: **Electrotransport Device Having a Reservoir Housing Having a Flexible
Conductive Element**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PRE-APPEAL BRIEF REQUEST FOR REVIEW

For the reasons discussed in the attached sheets, applicant respectfully requests a pre-appeal brief conference for review and reconsideration of the official action issued January 8, 2009 in which claims 17 to 22 of the above-identified patent application were rejected.

This request is being filed with a notice of appeal, no amendments are being filed with this request, and no more than five sheets of remarks are attached.

REMARKS

Two rejections under 35 U.S.C. § 102(b), or, alternatively, under 35 U.S.C. § 103(a), were made in the official action issued January 8, 2009. First, claims 17 to 22 were rejected under 35 U.S.C. § 102(b) as allegedly anticipated by, or, alternatively, under 35 U.S.C. § 103(a) as allegedly rendered obvious by, U.S. patent number 5,857,994 (“the Flower patent”). The Flower patent fails to describe or suggest all the limitations of the claims, however, and thus fails to anticipate, and render obvious, the claimed electrotransport delivery devices.

Independent claim 17 recites an electrotransport device comprising a reservoir and a non-conductive housing for the reservoir that comprises a substantially flexible electrically conductive element integrally molded within the non-conductive housing. The electrically conductive element comprises an electrode end positioned within the non-conductive housing and coated with an electrode coating; a connecting portion coated with a connecting coating comprising a flexible polymer; and a contact end positioned outside the non-conductive housing and coated with a contact coating. A substantially liquid and moisture-impermeable bond is created between the material forming the non-conductive housing and the conductive element.

Contrary to the Office’s assertions, the Flower patent fails to suggest, much less describe, such electrotransport devices. For example, the Flower patent does not describe electrotransport devices in which an electrically conductive element is *integrally molded* within a reservoir housing and in which an electrode end of the conductive element is positioned *within* the housing and a contact end of the conductive element is positioned *outside* the housing. Rather, the Flower patent describes an iontophoretic drug delivery device that includes a controller 2 and a patch 4 containing active electrode 8 and return electrode 10.¹ The controller is electrically coupled to the patch using electronic interconnectors 26, which can be a printed flexible circuit, metal foils, wires, tabs, or electrically conductive adhesives.² Electronic interconnectors 26 do not correspond to the electrically conductive element of the claimed devices, however, and patch 4 does not correspond to the non-conductive housing of the claimed devices. As shown in figure 1 of the Flower patent, the electronic interconnectors 26 are not *integrally molded* within patch 4,

¹ Figures 1 and 2 and col. 4, lines 15 to 30.

² Col. 4, lines 27 to 30.

electrode ends of the interconnectors 26 are not positioned *within* the patch, and contact ends of interconnectors 26 are not positioned *outside* the patch. As the Flower patent teaches, conductive pads 34 on extending narrow tab 32 are the portion of the device that *extend outside* of patch 4 to electrically connect electrodes 8 and 10 to the controller 2. The patent explains that conductive pads 34 are “exposed,” which those skilled in the art would readily understand to mean that a portion of each pad is on the *outside* of the patch, in contrast to the electrical connectors, which are not described as “exposed.” In this regard, the patent teaches that “electrical connectors 26 may be one or more conductive paths extending from the electrodes 8 and 10 to exposed conductive pads 34.”³ Accordingly, the electrical connectors 26 are located *within* patch 4 and extend from electrodes 8 and 10 to the conductive pads 34, a portion of each of which is located outside of patch 4 to electrically connect electrodes 8 and 10 to controller 2.⁴ Conductive pads 34, rather than the interconnectors, thus extend outside of patch 4 to connect electrodes 8 and 10 to controller 2, and the interconnectors 26 are therefore not integrally molded within patch 4 so that one end is positioned within the patch 4 and the other end positioned outside patch 4.

The Flower patent also does not describe electrotransport devices comprising an electrically conductive element in which an electrode end of the element is coated with an electrode coating, a contact end of the conductive element is coated with a contact coating, and a connecting portion of the conductive element is coated with a connection coating comprising a flexible polymer. In contrast to the Office’s assertions, the Flower patent, in fact, lacks any teaching, description, or suggestion of coatings for any portion of interconnectors 26.

The Flower patent thus fails to describe or suggest every limitation recited in the pending claims, and, accordingly, fails to anticipate the claimed electrotransport devices. Moreover, those of ordinary skill in the art would have had no reason to design and produce electrotransport devices having the features recited in the claims before applicant’s invention. Nothing in the Flower patent, when considered in view of the state of the art at the time of the invention, would have led those skilled in the art to fabricate electrotransport devices in which an electrically conductive element is integrally molded within a non-conductive housing such that one end of

³ Col. 4, lines 63 to 65.

⁴ Figure 4.

the element is positioned within the non-conductive housing and the other end is positioned outside the non-conductive housing. The claimed devices therefore would not have been obvious at the time of the invention.⁵

Claims 17 to 22 have also been rejected under 35 U.S.C. § 102(b) as allegedly anticipated by, or, alternatively, under 35 U.S.C. § 103(a) as allegedly rendered obvious by, U.S. patent number 6,915,159 (“the Kuribayshi patent”). Similar to the Flower patent, the Kuribayshi patent fails to describe or suggest all the limitations of the claims, and thus fails to anticipate, and render obvious, the claimed electrotransport delivery devices.

The Kuribayshi patent describes an electrode structure for iontophoresis devices in which a portion of an electrode layer (designated as 2 in Figures 1 and 2; Figures 4, 5, and 6 designate the anode electrode layer as 14 and the cathode electrode layer as 15) is located between an insulating layer 3 and a backing 1. As shown in Figure 3, portions of the electrode layer 2 make direct contact with a conductive layer 9 and with a cover member 8 where the insulating layer 3 is not present.⁶

The electrode layers of the devices described in the Kuribayshi patent (14 and 15 depicted in figure 6(c) and 2 in figure 1) do not correspond to the claimed electrically conductive element, and backing 1 does not correspond to the claimed non-conductive housing. Figures 1(c), 3, and 6(c) of the Kuribayshi patent clearly illustrate that electrode layers 14 and 15 are not integrally molded within a non-conductive housing. Moreover, a first end of electrode layers 14 and 15 is not located within a housing and a second end of electrode layers 14 and 15 is not located outside a housing. As seen in figures 3 and 6(c), electrode layers 14 and 15 are located between insulating layer 3 and backing 1, and portions of the electrode layers 14 and 15 make direct contact with conductive layer 9 and with cover member 8 where insulating layer 3 is not present. The entirety of electrode layers 14 and 15 is on the inner portion of backing 1. Accordingly, the electrode layers 14 and 15 are necessarily *not integrally molded* within a non-

⁵ To establish *prima facie* obviousness, the Patent Office must demonstrate that a cited prior art reference or combination of references teaches or suggests all the limitations of the claims.⁵ The Patent Office must also identify “a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does.”⁵ In other words, the Office must identify “an apparent reason to combine the known elements in the fashion claimed by the patent at issue.”⁵

⁶ Figures 2, 3, and 6(c) and col. 5, lines 59 to 65.

conductive housing, and, thus, a first portion of the electrode layer is not located within a housing and a second portion of the electrode layer is not located on the outside of a housing.

Moreover, the Kuribayshi patent also does not describe electrotransport devices comprising an electrically conductive element in which an electrode end of the element is coated with an electrode coating, a contact end of the conductive element is coated with a contact coating, and a connecting portion of the conductive element is coated with a connection coating comprising a flexible polymer. In contrast to the Office's assertions, the Kuribayshi patent, in fact, lacks any teaching, description, or suggestion of coatings for any portion of electrode layers 2, 14, and 15.

The Kuribayshi patent thus fails to describe or suggest every limitation of the pending claims, and, therefore, fails to anticipate the claimed electrotransport devices. In addition, nothing in the Kuribayshi patent, when considered in view of the state of the art at the time of the invention, would have led those skilled in the art to produce electrotransport devices in which an electrically conductive element is integrally molded within a non-conductive housing such that one end of the element is positioned within the non-conductive housing and the other end is positioned outside the non-conductive housing. The claimed devices therefore would not have been obvious at the time of the invention. Withdrawal of the rejections for alleged anticipation and/or obviousness is therefore respectfully requested.

Alleged Indefiniteness

Claim 22 has been rejected under 35 U.S.C. § 112, second paragraph because insufficient antecedent basis allegedly exists for the phrase "the connection coating" recited in the claim. Claim 22 depends from claim 17, which recites "a connecting portion coated with a connection coating," however. Antecedent basis therefore exists in claim 17 for the phrase "the connection coating" recited in claim 22. Applicant accordingly, respectfully, requests withdrawal of the rejection.

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Application No.: **10/814,705**

Respectfully submitted,

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